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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/585,613 | 07/11/2006 | Seiichiro Miyahara | DK-US065158 | 8526 |

22919 7590 08/31/2010

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| EXAMINER | |
|---|---|
| BOWERS, NATHAN ANDREW | |
| ART UNIT | PAPER NUMBER |
| 1797 | |
| MAIL DATE | DELIVERY MODE |
| 08/31/2010 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/585,613 | MIYAHARA, SEIICHIRO | |
| | Examiner | Art Unit | |
| | NATHAN A. BOWERS | 1797 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *3-7,10,11 and 13-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7,10,11 and 13-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 June 2010 has been entered.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 3-7, 10, 11 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbera-Guillem (US 20040029266) in view of Copeland (US 6429008), Hesse (US 4336329) and Zeitlin (EP 0156176).

Barbera-Guillem discloses a temperature control device for culturing fungi at a predetermined culturing temperature. Cells are grown within a cassette (Figure 1:100) that holds a culture medium. Paragraph [0327] states that the cassette is positioned adjacent to a Peltier device (Figure 89:1060) and conductor plates (Figure 89:1070) that both heat and cool the cassette. Control electronics (Figure 91:1055) include both a temperature setting unit and a temperature control unit configured to control the operation of the Peltier device. Although the Peltier devices of Barbera-Guillem are capable of functioning as both a heating mechanism and a cooling mechanism, Barbera-Guillem does not expressly state that both heating and cooling mechanisms are simultaneously provided for each cassette.

Hesse discloses a container (Figure 1:10) for culturing fungi at a desired temperature. Column 4, lines 6-26 state that both heater elements (Figure 2:13) and cooling coils (Figure 2:14) are provided to affect the temperature within the container.

Barbera-Guillem and Hesse are analogous art because they are from the same field of endeavor regarding cell culture systems.

At the time of the invention, it would have been obvious to ensure that each cassette disclosed by Barbera-Guillem is in communication with at least one heating mechanism and at least one cooling mechanism. As evidenced by Hesse, this configuration is functionally equivalent to the use of a single Peltier element serving dual heating and cooling functions. One of ordinary skill would have recognized that the simultaneous provision of heating and cooling mechanisms would have allowed for quick and precise temperature change.

The combination of Barbera-Guillem and Hesse still differs from Applicant's claimed invention because Barbera-Guillem does not disclose a specific temperature range.

Copeland discloses a cassette for culturing fungi comprising a temperature control system. Column 14, lines 11-18 indicate that temperatures between 20 and 45 degrees Celsius allow for the efficient growth of most fungal cells.

Barbera-Guillem and Copeland are analogous art because they are from the same field of endeavor regarding cell culture systems.

At the time of the invention, it would have been obvious to ensure that each cassette disclosed by Barbera-Guillem is maintained at temperatures between 20 and 45 degrees Celsius. More specifically, one of ordinary skill in the art would have been motivated to periodically switch between 27 degrees Celsius, 30-32 degrees Celsius and 35-37 degrees Celsius based on the immediate needs of the growing cells. It is well within the purview of one of ordinary skill to identify through routine experimentation the most desirable individual temperatures within a localized temperature range described by the prior art as suitable for cell growth.

The combination of Barbera-Guillem, Hesse and Copeland still differs from Applicant's claimed invention because Barbera-Guillem does not that each temperature control device comprises a cassette in communication with a separate temperature setting unit and heating-and-cooling control unit.

Zeitlin discloses an incubator system wherein a plurality of incubators (Figure 1:15) are provided with an associated automated controller (Figure 1:10), wherein each controller includes a temperature-setting unit and a heating-and-cooling unit. For example, Zeitlin teaches on page 8, lines 10-23 that sets of initial conditions for each control variable (e.g. temperature) are assigned to each individual controller through programs automatically loaded into a memory unit. Zeitlin additionally teaches on page 7, lines 8-20 that local controllers 10, 11, 12 and 13 serve to measure, regulate and correct temperature within an associated incubator in real time. Page 7, lines 21-28 further indicates that the temperature control units are connected to each other via a

communication unit comprising various links (Figure 1:16) and a central controller (Figure 1:20).

Barbera-Guillem and Zeitlin are analogous art because they are from the same field of endeavor regarding cell culture systems.

At the time of the invention, it would have been obvious to ensure that each incubator cassette disclosed by Barbera-Guillem was coupled to a heating-and-cooling control unit and a temperature-setting unit connected to other control units through a communication unit. As evidenced by Zeitlin, this controller configuration is well known in the art and effective for regulating temperatures within individual incubators. Zeitlin teaches that heating-and-cooling control units coupled to individual incubators allows for improved sensitivity and response when monitoring conditions within the cell culture.

### ***Response to Arguments***

Applicant's arguments filed 10 December 2009 with respect to the 35 U.S.C. 103 rejections involving the combination of Barbera-Guillem, Copeland and Hesse have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Barbera-Guillem, Copeland, Hesse and Zeitlin.

The Zeitlin reference addresses the deficiencies of Barbera-Guillem by indicating that it is well known in the art to provide a plurality of incubators with individual temperature control means connected to other temperature control means via a communication unit.

***Conclusion***

This is a non-final rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nathan A Bowers/
Examiner, Art Unit 1797